REMARKS/ARGUMENTS

Claims 1-21 are pending after entry of this paper. Claims 1-21 have been subjected to election of an invention group for prosecution on the merits under 35 U.S.C. §§121 & 372. Claims 1-7 and 11-21 have been amended to place them in proper format under the U.S. patent practice. No new matter has been introduced by these amendments.

Response to Restriction Requirement under 35 U.S.C. §§121 & 372

Claims 1-21 have been subjected to election of an invention for prosecution on the merits under 35 U.S.C. §§ 121 & 372. In the Examiner's opinion, as set forth in the Detailed Action, the application contains inventions or groups of inventions, which are not linked to form a single general inventive concept under PCT Rule 13.1. The Office Action alleges that the application contains claims directed to five (5) patentably distinct inventions as follows:

Group I: Claims 1, 2 and 11-20, drawn to a polypeptide specifically inhibiting Akt activity.

Group II: Claims 3-6, drawn to a gene DNA encoding a polypeptide.

Group III: Claim 7, drawn to a method of producing a polypeptide.

Group IV: Claims 8-10, drawn to an antibody.

Group V: Claim 21, drawn to a method for specifically inhibiting Akt activity.

Depending on the group elected, the Examiner also requested an **election of single species** of (a) a polypeptide sequence, (b) a DNA sequence, and (c) the type of cancer to be treated.

Applicants respectfully request that the Restriction Requirement be withdrawn and all claims be examined together on the merits. Nonetheless, in response to the Restriction Requirement, the applicant provisionally elects **Group I** including **claims 1, 2, and 11-20.** Within Group I, the applicant also provisional elects **species of polypeptide provided in SEQ ID NO. 1 to treat "leukemia."** The applicant respectfully disagrees with the restriction requirement imposed by the Examiner and the characterizations made of the claimed invention. For that reason, this election is made **with traverse**.

First, it is the Examiner's position that the election of species is appropriate because "these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1." (Office Action; p. 4). The applicant respectfully disagrees with the Examiner's position.

Applicants respectfully submit that **five** peptide sequences presented as SEQ ID NOs: 1, 3, 5, 7 or 9 should be examined on the merits together because not only it is not burdensome but examining so few sequences together is, in fact, encouraged by the Director. According to MPEP 803.04,

> [t]o further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Director has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. . . .
> It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. (emphasis added)

Thus, applicants respectfully assert that in accordance with MPEP 803.04, the required election of peptide sequences selected from five **short** peptide sequences (SEQ ID NOs:

1, 3, 5, 7 or 9) should be reconsidered and waived in recognition of the "Director's" desire to promote and aid the biotechnology industry.

Furthermore, with regard to the imposed single "type of cancer disease condition" election, applicants respectfully assert that such election unduly limits the claimed invention because the peptide(s) of the present invention (*e.g.*, SEQ ID NO: 1) have an antitumor effect against various types of malignancies. As described in the specification, Akt activation is involved in breast cancer, lung cancer, prostate cancer, ovarian cancer, leukemia and lymphoid tumor. As Akt activity is raised in these malignancies, Akt activation is considered to a cause of these malignancies. By inhibiting Akt activation, the antitumor agent of the present invention exerts an antitumor action not only against leukemia but also against other types of cancers. For example, as shown in the supplemental experimental data, the peptide comprising SEQ ID NO: 1 exerted its cell-growth inhibition action against all types of cancer cells used in the experiment (23 cell lines from lung cancer, ovarian cancer, tumor of the central nervous system, or breast cancer).

In summary, applicants respectfully traverse the requirement for election on the grounds that (1) examining 5 sequences presented in SEQ ID NOs.: 1, 3, 5, 7 or 9 is not burdensome and permitted by the Patent Office under the directive presented in MPEP 803.04 and (2) limiting the invention to one form of cancer malignancy unduly limits the invention. Therefore, reconsideration and withdrawal of the restriction/election is respectfully requested.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-4827**, Order No. 1004331.036US.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No.**50-4827**, Order No. 1004331.036US.

Respectfully submitted,
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Supplemental Data

Akt-in inhibits various human cancer cell growth

Methods: Effect of a peptide comprising Akt binding domain of TCL1 (AVTDHPDRLWAWEKF, named '*Akt-in*') on human cancer cell growth were investigated. Cancer cells indicated in the following Figures were seeded into each well of 96-well culture plate. Control peptide (TAT-EKQHAWLPLTIE) or TAT-*Akt-in* (TAT-AVTDHPDRLWAWEKF) was added at the concentration of 10^{-4}-10^{-8} M. Forty eight hours later, Sulforhodamine regent was added, incubated at 37C, and the absorbance was determined using a microplate reader.

Results: Results of the proliferation assays are shown in Figs. A-D. TAT-*Akt-in* inhibits various human cancer cell growth at around 10^{-4} M of concentration (Fig. A: lung cancer, Fig. B: ovarian cancer, Fig. C: CNS tumor, Fig. D: breast cancer). Control peptide showed no inhibitory effect at 10^{-4} M of concentration (data not shown).

Fig. A. Effects of *Akt-in* on lung cancer cell lines.

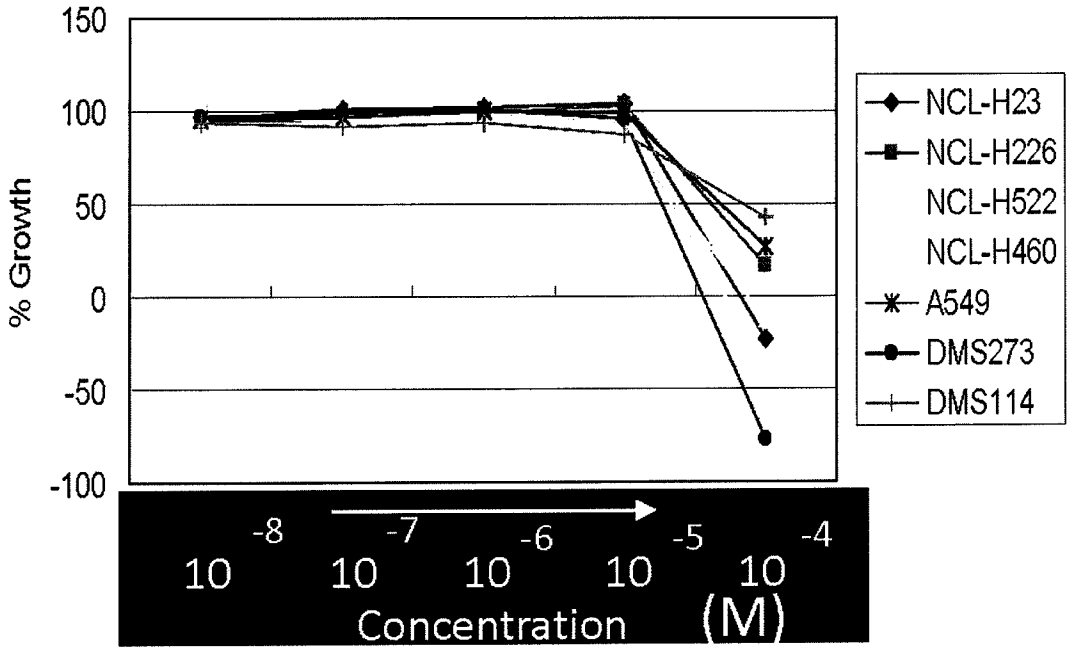

Fig. B. Effects of *Akt-in* on ovarian cancer cell lines.

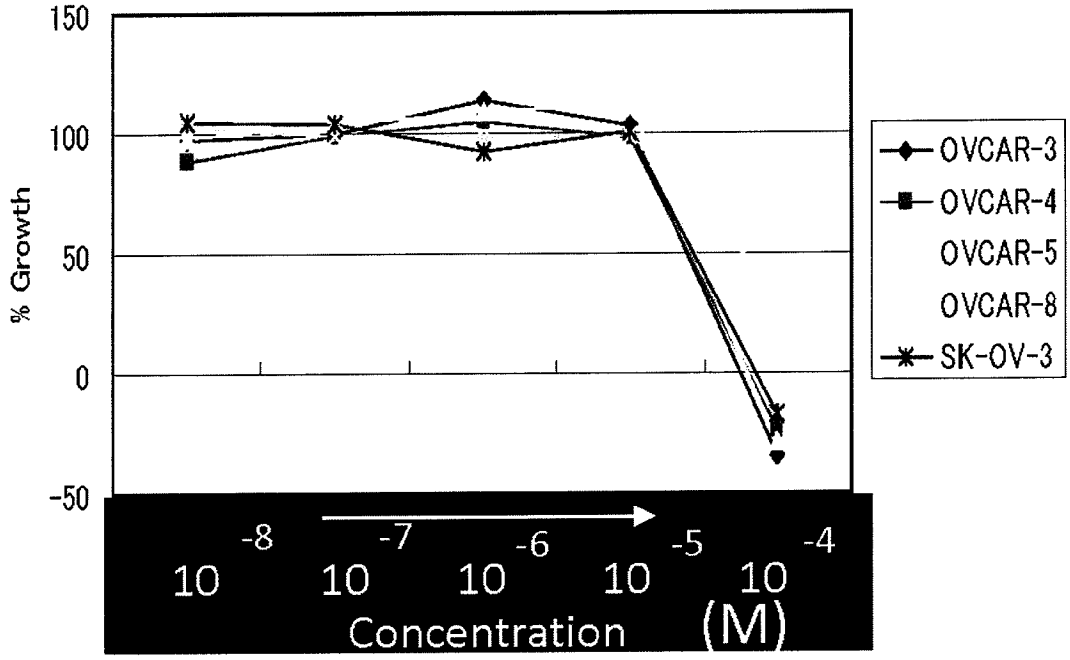

Fig. C. Effects of *Akt-in* on CNS tumor cell lines.

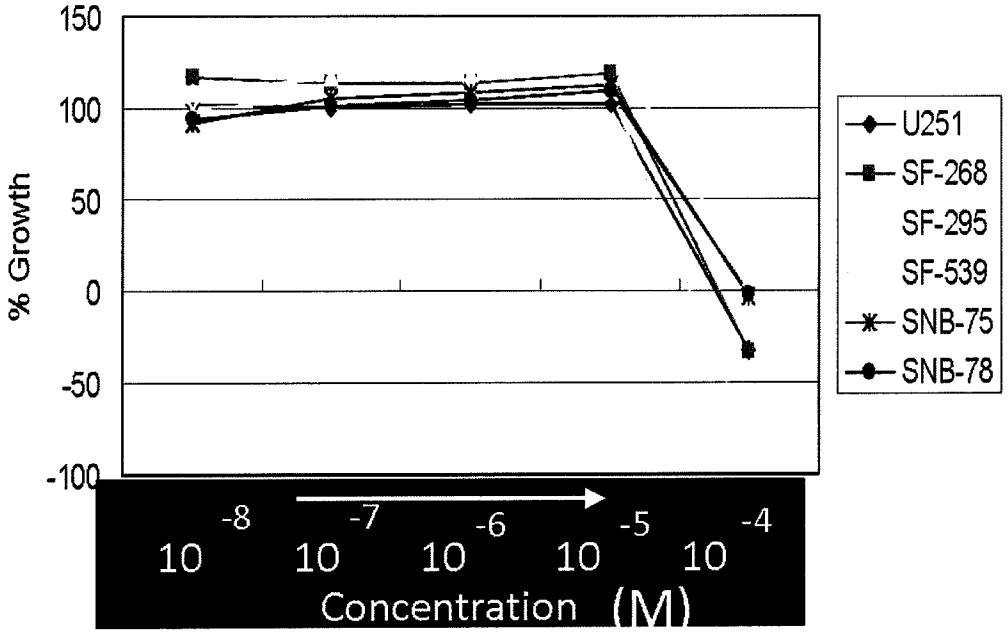

Fig. D. Effects of *Akt-in* on breast cancer cell lines.